



January 7, 2022

EKOS Corporation
Jocelyn Kersten
Regulatory Affairs Manager
22030 20th Avenue SE, Suite 101
Bothell, Washington 98021

Re: K041629
Trade/Device Name: Lysus Infusion System
Regulation Number: 21 CFR 870.5150
Regulation Name: Embolectomy catheter
Regulatory Class: Class II
Product Code: QEY, KRA

Dear Jocelyn Kersten:

The Food and Drug Administration (FDA) is sending this letter to notify you of an administrative change related to your previous substantial equivalence (SE) determination letter dated August 6, 2004. Specifically, FDA is updating this SE Letter as an administrative correction because FDA has created a new product code to better categorize your device technology.

Please note that the 510(k) submission was not re-reviewed. For questions regarding this letter please contact Gregory O'Connell, OHT2: Office of Cardiovascular Devices, (301) 796-6075, Gregory.Oconnell@FDA.HHS.gov.

Sincerely,

Gregory W.
O'Connell -S

Digitally signed by
Gregory W.
O'Connell -S
Date: 2022.01.07
13:31:33 -05'00'

Gregory O'Connell
Assistant Director
DHT2C: Division of Coronary
and Peripheral Intervention Devices
OHT2: Office of Cardiovascular Devices
Office of Product Evaluation and Quality
Center for Devices and Radiological Health



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

AUG - 6 2004

EKOS Corporation
c/o Ms. Jocelyn Kersten
Director, Regulatory Affairs
22030 20th Avenue, Suite 101
Bothell, WA 98021

Re: K041629
Lysus Infusion System
Regulation Number: 21 CFR 870.1210
Regulation Name: Continuous Flush Catheter
Regulatory Class: Class II (two)
Product Code: KRA
Dated: June 15, 2004
Received: June 16, 2004

Dear Ms. Kersten:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

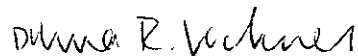
If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.


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Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050. This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (301) 594-4648. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address <http://www.fda.gov/cdrh/dsma/dsmamain.html>

Sincerely yours,



 Bram D. Zuckerman, M.D.
Director
Division of Cardiovascular Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): K041629

Device Name: Lysus® Infusion System

Indications For Use: The Lysus® Infusion System is intended for the controlled and selective infusion of physician-specified fluids, including thrombolytics, into the peripheral vasculature.

Prescription Use X
(Part 21 CFR 801 Subpart D)

AND/OR

Over-The-Counter Use _____
(21 CFR 807 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Danna R. Vichner
(Division Sign-Off)
Division of Cardiovascular Devices

510(k) Number K041629

AUG - 6 2004

9 510(k) Summary

Applicant Name: EKOS Corporation

Address: 22030 20th Ave. SE, Suite 101
Bothell, WA 98021

Contact Person: Jocelyn Kersten
Director, Regulatory Affairs

Telephone: (425) 482-1108 X 287

Fax: (425) 482-1109

Device: Lysus® Infusion System

Classification: CFR 870.1210 – Continuous Flush Catheter

Panel: Cardiovascular

Product Code: KRA

Intended Use: The Lysus® Infusion System is intended for the controlled and selective infusion of physician-specified fluids, including thrombolytics, into the peripheral vasculature.

Device Description: The Lysus® Infusion System is an infusion catheter system designed to deliver fluids via a multi sidehole catheter. The fluid is dispersed via multiple ultrasound transducers distributed linearly along the length of an ultrasound core which is placed into the center lumen of the catheter. This device is intended to deliver physician-specified agents or fluids into the peripheral vasculature.

Predicate Basis: The Lysus® Infusion System is substantially equivalent to other legally marketed devices. These devices include

- EKOS Corporation: EKOS Peripheral Infusion System (K030367, K033214)
- Merit Medical: Fountain Infusion Catheter (K974067, K991619, K992231)
- Micro Therapeutics: Cragg/McNamara Infusion Catheter (K964868)
- Angiodynamics: SpeedLyser Infusion Catheter Kit (K033443)

Performance: EKOS has conducted preclinical bench and animal studies with the Lysus® Infusion System. These studies demonstrate that the performance of the Lysus® Infusion System meets its design specifications and is safe and effective for its intended use.